

REMARKS/ARGUMENTS

Claim Rejections – 35 C.F.R. § 112, first paragraph

The Examiner rejected Claims 23-25 as not enabled stating that “the specification, while being enabling for treating psoriasis or the actual diseases contemplated or known to be treatable via the instant mechanisms, does not reasonably provide enablement for all and every disease known and unknown that possibly could be treated via said mechanisms.” (p. 2 of the September 15, 2005 Office Action). The Examiner does not, however, provide any reasoning why one of ordinary skill in the art would not be able to determine without undue experimentation which diseases are treatable by inhibiting a cysteine protease (Claim 23) or by inhibiting cathepsin S in particular (Claims 24 and 25).

The Patent Office has the burden of making the prima facie case for why a person of ordinary skill in the art would not be able to make and use the invention without undue experimentation. MPEP 2164.04 requires that the examiner “... specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation.” MPEP 2164.04 also states that “specific technical reasons are always required.” In this case, the Examiner has not provided any technical reasons why the invention is not enabled or given reasons why one skilled in the art could not supply the information without undue experimentation.

In fact, the Examiner merely concludes that “... the instant specification does not provide sufficient data to support such broad claims such that one of ordinary skill in the art would have to practice unduly to determine which diseases are treatable as claimed.” (p. 2 of the September 15, 2005 Office Action). The Applicants respectfully argue that it is the burden of the Patent Office to provide reasons why one of ordinary skill in the art would not know how to determine which diseases are treatable as claimed. In addition, the Examiner has discussed none of the

Wands factors to show how she came to the conclusion that there is an undue burden of experimentation on one of ordinary skill in the art to determine which diseases are treatable as claimed.

Even if the Examiner had stated a *prima facie* case, the Applicants argue that Claims 23-25 are enabled. The Applicants' obligation is to *teach* one of ordinary skill in the art how to make and use the invention. They are not obligated to assess the role of a cysteine protease (Claim 23) or cathepsin S (Claims 24 and 25) in every possible disease where they have given the tools and/or one of ordinary skill in the art would know how to make and use the invention. In fact, the standard is "whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art." M.P.E.P. § 2164.08 (b). A person of ordinary skill in the art would know how to use animal models to determine the role of a cysteine protease (Claim 23) or cathepsin S (Claims 24 and 25) in a particular disease.

While the Applicants have the burden to teach how to make and use the invention, they are not required to include in the application what is known in the art. (See *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991), as cited in MPEP § 2164.01, which states that "[a] patent need not teach, and preferably omits, what is well known in the art.") The Applicants direct the Examiner's attention to M.P.E.P. § 2164.03 which states that "... even in unpredictable arts, a disclosure of every operable species is not required." Therefore, the Examiner may not require the Applicants to disclose every cysteine protease-mediated disease that is known or knowable, without undue experimentation, to one of ordinary skill in the art.

In addition to arguing Claims 23-25 are not enabled, the Examiner states in the Office Action that "[t]he office is now considering these mechanism claims to be reach through claims." (p. 2 of the September 15, 2005 Office Action) The Applicants respectfully submit that the claims are not, in fact, reach-through claims. The courts identify a claim as a reach-through

claim, and subsequently invalidating it, where an applicant has claimed any compound that inhibits a particular target without actually identifying the structure of the compound and only defining that compound by its ability to bind to the target. In this application, the Applicants have clearly identified which compounds would inhibit a cysteine protease. The Applicants can find no reference in the MPEP or in case law to support the Examiner's assertion that Claims 23-25 are reach-through claims.

Finally, the Examiner argues in the office action that the claims are not enabled because "[o]ne cannot ascertain their [the claims'] metes and bounds as written." (p. 2 of the September 15, 2005 Office Action) The metes and bounds of the claims are clearly ascertainable. Claims 23-25 are directed to methods of treating a disease that is mediated by a cysteine protease, particularly cathepsins K, S, or F (Claim 23) or by cathepsin S (Claims 24 and 25). The boundaries of Claims 23-25 regarding which diseases are included or excluded are clearly defined by the ability of a compound to inhibit a cysteine protease. A disease that is not mediated by a cysteine protease is not included in the scope.

CONCLUSION

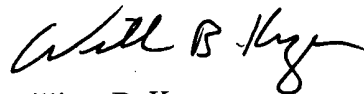
The Applicants believe that the § 112 rejection for non-enablement of Claims 23-25 is improper and that all the claims are in a condition for allowance. Applicants respectfully request that the claims be allowed.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Appln. No. 10/603,437
Amdt dated March 13, 2006
Reply to Office Action dated 09/15/06

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5015.

Respectfully submitted,



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